**Description**

**A COMPOSITION FOR THE TREATMENT OF TRIGEMINAL NEURALGIA**

**Technical Field**

The invention relates to a composition formed for the treatment of trigeminal neuralgia.

**State of the Art**

Trigeminal nerve is the sensory nerve on two sides of the face. It enables us to perceive the sensation in the half of the face. Trigeminal neuralgia is a disorder originating from the trigeminal nerve of 12 nerve pairs extending from the brain. Trigeminal nerve has three main branches from the temporal ganglion to the region around the eye and forehead, upper lip-maxilla and lower lip-mandibula. In the trigeminal neuralgia patients, one or two of these three branches are affected.

In the region in the half of the face affected by neuralgia, the intolerable pains are present as transient, momentary sensation of being stabbed or as the sensation of electric shock. These transient and one sided pains are of a recurrent character. These pains may be triggered by the wind, heat, cold foods, shaving, sometimes talking and sometimes even swallowing.

According to the state of the art, generally the drug therapy is employed for the treatment of the trigeminal neuralgia. In cases where the drug therapy is insufficient, the method of burning the nerve fibers responsible for the conduction of pain by means of radiofrequency thermocoagulation is attempted. The examinations are made with the assumption that the nerve is affected over the distance from the face to its nucleus in the brain to which it extends. In the brain, there may be pathology in the cerebellopontine angle or posterior fossa (tumor or vascular anomalies). Even though rarely encountered, first this possibility should be ruled out. These conditions, which are very rarely encountered, may be eliminated by the neurological examination. If these causes underlie trigeminal neuralgia, their treatment may include the surgical methods.

According to the state of the art, the trigeminal neuralgia is currently treated with cox-2 and FMO3 inhibitors. These medications used according to the state of the art have side effects such as the liver and kidney damage, and the increased internal bleeding risk and the irregularities of blood sugar are the effects likely to be observed in the medium term.

In the conventional neurology approach, the cause may not be found in majority of the trigeminal neuralgia patients. In the treatment of the trigeminal neuralgia, it is tried to suppress the abnormal stimulation in the nerve by using the medicaments. The drugs used for the treatment of epilepsy and neuropathic pain are often used as the first option. In case the inhibition may not be achieved with the drugs, there are the attempts of inhibition by way of direct intervention on the nerve. There are also the surgical interventions carried out inside the brain. There are the patients with pain inhibited at different stages. However, a considerable number of patients suffer pain despite all these interventions.

In my studies during the recent years, I have provided the solutions that do not require the drugs and any other intervention such as surgical operation, by revealing the area (starting point) where the nerve is primarily triggered in the patients. The results I obtained have shown that the basis of the neuralgia is not associated with the brain. The results obtained from the patients subjected to surgical operation also support this picture.

According to the state of the art, the invention no. EP1604680B1 entitled "Use of botulinum toxin in the treatment of neuralgia pain" relates to a botulinum toxin for use in a method for alleviating neuralgia pain in a human patient wherein the botulinum toxin is administered peripherally and wherein the neuralgia pain is not associated with a headache.

Further, according to the invention no. EP2155736B1 entitled "Novel carbamoyloxy arylalkanoyl arylpiperazine compound, pharmaceutical compositions comprising the compound and method for treating pain, anxiety and depression by administering the compound", there is provided a novel carbamoyloxy arylalkanoyl arylpiperazine derivative compound having abundant racemic or enantiomeric characteristics, represented by the Formula 1, and pharmaceutically available salts or hydrates thereof. Also, there are provided a pharmaceutical composition for treating pain (i.e. acute or chronic pain, neuropathic pain, inflammatory pain, diabetic pain, postherpetic neuralgia, etc.), anxiety or depression including an effective amount of the compound, and a method for treating pain, anxiety or depression in mammals by administering an effective amount of the compound to the mammals in need thereof.

Further, according to the invention no. US2003069300 entitled "Use of benzopyranols to treat neurological disorders", benzopyran derivatives and analogs are disclosed as useful for the treatment and/or prophylaxis of degenerative diseases such as Huntington's chorea, schizophrenia, neurological deficits associated with AIDS, sleep disorders (including circadian rhythm disorders, insomnia and narcolepsy), tics (e.g. Giles de la Tourette's syndrome), traumatic brain injury, tinnitus, neuralgia, especially trigeminal neuralgia, neuropathic pain, dental pain, cancer pain, inappropriate neuronal activity resulting in neurodysthesias in diseases such as diabetes, MS and motor neuron disease, ataxias, muscular rigidity (spasticity), temporomandibular joint dysfunction.

As a result, the presence of the need for a composition for treating the trigeminal neuralgia and the inadequacy of the existing solutions have made it necessary to perform an improvement in the relevant art.

**Object of the Invention**

In order to eliminate the disadvantages of the state of the art, an object of the invention is to provide effective pge-2 and cox-2 inhibition.

Another object of the invention is to trigger the production of beta-endorphine.

In order to achieve the aforesaid advantages, the invention is a composition for the treatment of the trigeminal neuralgia, said composition being obtained by the components selected from the group comprising 3,7-bis(2-hydroxyethyl)-8-(3-methyl-2-buten-1-yl)-4H-1-benzopyran-4-one, 3,5-bis(2-hydroxyethyl)-8-(3-methyl-2-buten-1-yl)-4H-1-benzopyran-4-one that are used individually or in combinations.

The structural and characteristic features and all the advantages of the invention will become more clearly understood from the detailed description provided below and therefore, the evaluation must be made taking this detailed description into consideration.

**Detailed Description of the Invention**

The invention is a composition for the treatment of trigeminal neuralgia. The semi-synthetic bioflavonol glycoside derivatives of the composition according to the invention provide effective pge-2 and cox-2 inhibition and trigger the production of beta-endorphine.

The composition according to the invention contains 3,7-bis(2-hydroxyethyl)-8-(3-methyl-2-buten-1-yl)-4H-1-benzopyran-4-one, 3,5-bis(2-hydroxyethyl)-8-(3-methyl-2-buten-1-yl)-4H-1-benzopyran-4-one.

Said formulation is obtained by a mixture of the aforesaid components according to the following ratios by weight:

22-78% 3,7-bis(2-hydroxyethyl)-8-(3-methyl-2-buten-1-yl)-4H-1-benzopyran-4-one,

78-22% 3,5-bis(2-hydroxyethyl)-8-(3-methyl-2-buten-1-yl)-4H-1-benzopyran-4-one

The composition is obtained from the aforesaid components selected from the aforesaid group and used according to the mentioned weight ratio ranges individually or in combinations.

Said invention also encompasses the use of said composition for treating the trigeminal neuralgia and the manufacture thereof for this purpose.

**CLAIMS**

1. A composition for the treatment of the trigeminal neuralgia, said composition being obtained by the components selected from the group comprising 3,7-bis(2-hydroxyethyl)-8-(3-methyl-2-buten-1-yl)-4H-1-benzopyran-4-one, 3,5-bis(2-hydroxyethyl)-8-(3-methyl-2-buten-1-yl)-4H-1-benzopyran-4-one that are used individually or in combinations.
2. A composition according to Claim 1 characterized in that it comprises 22-78% by weight 3,7-bis(2-hydroxyethyl)-8-(3-methyl-2-buten-1-yl)-4H-1-benzopyran-4-one.
3. A composition according to Claim 1 characterized in that it comprises 78-22% by weight 3,5-bis(2-hydroxyethyl)-8-(3-methyl-2-buten-1-yl)-4H-1-benzopyran-4-one.
4. Use of the components according to Claims 1 to 3 obtained individually or in combinations from the group consisting of 3,7-bis(2-hydroxyethyl)-8-(3-methyl-2-buten-1-yl)-4H-1-benzopyran-4-one, 3,5-bis(2-hydroxyethyl)-8-(3-methyl-2-buten-1-yl)-4H-1-benzopyran-4-one **for the manufacture of a composition for treating the trigeminal neuralgia**.

**ABSTRACT**

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The invention relates to a composition formed for the treatment of trigeminal neuralgia.

No figure.